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| APPLICATION NO.                                                                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/520,078                                                                       | 04/04/2005  | Jamila Najib         | BJS-3665-126        | 9205             |
| 23117                                                                            | 7590        | 02/26/2009           | EXAMINER            |                  |
| NIXON & VANDERHYE, PC<br>901 NORTH GLEBE ROAD, 11TH FLOOR<br>ARLINGTON, VA 22203 |             |                      |                     | ZAREK, PAUL E    |
| ART UNIT                                                                         |             | PAPER NUMBER         |                     |                  |
| 1617                                                                             |             |                      |                     |                  |
| MAIL DATE                                                                        |             | DELIVERY MODE        |                     |                  |
| 02/26/2009                                                                       |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/520,078             | NAJIB ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Paul Zarek             | 1617                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 November 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 38,39,41-62,65,68 and 69 is/are pending in the application.  
 4a) Of the above claim(s) 68 and 69 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 38,39,41-62, and 65 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 05 January 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/31/2008</u> .                                              | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 38, 39, 41-62, 65, and 68 have been amended, Claims 40, 63, 64, 66, and 67 have been added, and Claim 69 has been cancelled by the Applicant in correspondence filed on 12/31/2008. Claims 38, 39, 41-62, 65, 68, and 69 are currently pending. Claims 68 and 69 are withdrawn as being drawn to a nonelected Group. This is the second Office Action on the merits of the claim(s).

## **RESPONSE TO ARGUMENTS**

2. Applicants expressed confusion with respect to which claims were examined and which were withdrawn in the Office Action mailed on 08/22/2008. Examiner regrets the confusion. Claims 38, 39, 41-62, and 65 are herein examined on the merits.

3. Claims 38 and 39 were objected to because said claims disclosed a formula I that could not be reconciled ( $X_2$  was –H and linked to the propenyl chain). This objection is moot in light of amendments to Claims 38 and 39.

4. Claims 38-60 and 63-67 were rejected under 35 U.S.C. 112, first paragraph, because the specification did not fully enable hydrates of formula I. This rejection is moot in light of amendments to Claims 38 and 39.

5. Claims 38-67 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for being drawn to compounds to treat various pathologies, and the language “associated with”. These rejections are moot in light of amendments to Claims 38 and 29.

6. Claims 38-40, 42, 44, 46-48, 56, 58, 63-65, and 67 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vanstone, et al. (US Patent No. 4,190,671, already of record).

Applicants traverse this rejection on the grounds that Vanstone, et al., do not render obvious the claimed formula I. Specifically, there is none of groups 1 or 2 in the compound taught by Vanstone, et al. Examiner finds Applicants' arguments persuasive, and this rejection is withdrawn.

7. Claims 38, 61, and 62 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 5, and 10, respectively of copending Application No. 11/493,040. Applicants traverse this rejection on the grounds that the claims of the '040 application require the presence of an additional therapeutically active agent, a limitation that is absent in the instant application. This argument is found persuasive, and the rejection is withdrawn.

8. Claims 38, 39, 61, and 62 were provisionally rejected under 35 U.S.C. Double Patenting as claiming the same invention as that of claims 69, 70, 96, and 97, respectively of copending Application No. 10/520,079. Applicants' request to hold this rejection in abeyance until such time as allowable subject matter is indicated is acknowledged. Until such time, however, the rejection is maintained.

9. Claim 38 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,385,082. Applicants' request to hold this rejection in abeyance until such time as allowable subject matter is indicated is acknowledged. Until such time, however, the rejection is maintained.

10. **Below are listed new grounds of rejection that are not necessitated by amendment to the claims. Therefore, this office action is considered non-final.**

***Claim Rejections - 35 USC § 112 (1<sup>st</sup> paragraph)***

11. The text of 35 U.S.C. § 112, first paragraph, can be found in a prior Office action.

12. Claims 38, 39, 41-62, and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 38 and 39 (from which all other claims depend) recite the limitation that the compound of formula I be in a pharmaceutical composition with a "pharmaceutically acceptable support". Applicants do not define what is meant by a "pharmaceutically acceptable support," and provide no examples of formula I in a "pharmaceutically acceptable support." Therefore, the rejected claims lack written description for "pharmaceutically acceptable support."

***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> paragraph)***

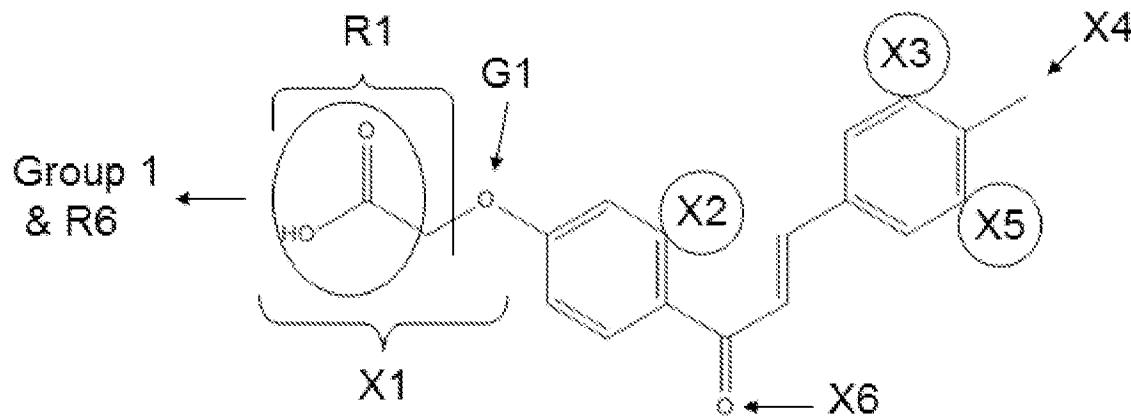
13. The text of 35 U.S.C. § 112, second paragraph, can be found in a prior Office action.

14. Claims 38, 39, 41-62, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 38 and 39 (from which all other claims depend) recite the limitation that the compound of formula I be in a pharmaceutical composition with a

“pharmaceutically acceptable support.” Applicants do not define what is meant by a “pharmaceutically acceptable support.” Therefore it is unclear what is meant by “pharmaceutically acceptable support” and the claims are, hence, indefinite.

***Claim Rejections - 35 USC § 103***

15. The text of 35 U.S.C. § 103 can be found in a prior Office action.
16. Claims 38, 42, 44, 46-48, 59, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanstone, et al. (US Patent 4,190,671, already of record), in view of King (Medical Chemistry: Principles and Practice, 1994, Chapter 14).
17. Claim 38 of the instant application is drawn to a composition comprising a derivative of formula I, with the exception of a derivative wherein X<sub>2</sub> is -H, and X<sub>1</sub> is -G<sub>1</sub>R<sub>1</sub> wherein G<sub>1</sub> is -O- and R<sub>1</sub> is -CH<sub>2</sub>COOH. Claims 42, 44, 46-48, and 59 limit the substituents of formula I. Claim 65 is drawn to a compound with an intended use of the compound for treatment. Examiner respectfully notes that statements of intended use do not limit the scope of the rejected claims. “If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention’s limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).” (MPEP § 2111.02)
18. Vanstone, et al., teach a derivative of formula I:



wherein X1 is  $-G_1-R_1$ , G1 is  $-O-$ , R1 is  $-CH_2$ -group I, Group1 is  $-COOR_6$ , R6, X2, X3, and, X5 are  $-H$ , X4= $R_4=-CH_3$ , and X6= $O$  (Example 12, col 9, line 51). The compound taught by Vanstone, et al., differ from the compounds of formula I recited in Claims in that Claims 38, 42, 44, 46-48, 59, and 65 states that the one of G1, G2, G3, G4, or G5 must be  $-S-$ . Claim 59 further recite an alkyl group on X3, not X4, as indicated by Vanstone, et al.

19. King teaches that  $-S-$  and  $-O-$  are bioisosteres of each other. In the absence of unexpected results, the simple replacement of  $-O-$  with  $-S-$  are considered obvious variants of each other. Also, moving the methyl group from X4 to X3 (Claim 59) is not considered a patentably distinguishing feature of the invention. Such compounds are isomers and are considered obvious variants of each other. “Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by  $-CH_2$ - groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties.” *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) (MPEP 2144.09(II)).

20. Therefore, the compounds encompassed by the rejected claims are *prima facie* obvious over Vanstone, et al., in view of King.

***Conclusion***

21. Claims 38, 39, 41-62, and 65 are rejected.  
22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/  
Primary Examiner, Art Unit 1625